OMB INFORMATION COLLECTION
SUPPORTING STATEMENT
0910-0052

Blood Establishment Registration and Product Listing, Form FDA 2830

JUSTIFICATION

1. Need and Legal Basis

The Food and Drug Administration (FDA) is requesting an extension of OMB Control No. 0910-0052 and OMB approval of the following information collection requirements in 21 CFR 607 (Tab A) and Form FDA 2830 (Tab B) for Blood Establishment Registration and Product Listing:

21 CFR 607.20(a)	Reporting	Requires certain establishments that engage in the manufacture of blood products to register and submit a list of blood products in commercial distribution.
21 CFR 607.21	Reporting	Requires establishments that engage in the manufacture of blood products to register within five days after beginning such operation and to submit a blood product listing at that time. In addition requires establishments to register annually and to update their product listing every June and December of each year.
21 CFR 607.22	Reporting	Requires the use of Form FDA 2830 for initial registration, for annual registration, and blood product listing.
21 CFR 607.25	Reporting	Indicates information required for establishment registration and blood product listing.
21 CFR 607.26	Reporting	Requires certain changes to be submitted as amendments to the establishment registration within 5 days of such changes.
21 CFR 607.30	Reporting	Requires establishments to update, every June and December, the blood product listing information, or at the discretion of the registrant at the time a change occurs.
21 CFR 607.31	Reporting	Requires additional blood product listing information, be provided upon FDA request.
21 CFR 607.40	Reporting	Requires foreign blood product establishments to register and submit the blood product listing information and the name of the individual for submitting the blood product listing information as well as the name, address, and phone number of the U.S. agent.

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360) (Tab C), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or a device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business, and all such establishments submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded or processed by him or her for commercial distribution.

All establishments engaged in the manufacture, preparation, propagation, or processing of human blood and blood products are subject to the requirements of section 510 as cited above. The regulations of establishment registration and product listing for blood establishments are found in 21 CFR Part 607.

After the initial registration and listing of human blood and blood products, re-registration by the establishment is required annually between November 15 and December 31 of each year. FDA sends an annual pre-printed Form FDA 2830 to each registrant by November 15 of each year to each previously registered establishment.

2. Information Users

The information obtained from the registration and listing of blood establishments on Form FDA 2830 is used by FDA, and other government agencies, to keep an accurate, up to date list of all blood establishments located in this country as well those in foreign countries. FDA uses this list for inspectional purposes as required by the Act. In addition, the data is used by industry, consumers, private institutions, etc., to keep up with the names and locations of blood establishments. Data from this file is used for many purposes and is essential for sending out letters by this agency and other government agencies regarding emerging health problems as they relate to the blood product industry. In addition, FDA uses information on the different types of listed products for regulatory and research purposes.

Through registration information on domestic and foreign blood establishments, regulatory agencies are able to determine the sources of specific products; this information is essential to the overall regulatory scheme designed to ensure the safety of the nation’s blood supply.

3. Improved Information Technology

The collection of information does currently involve the use of an automated, electronic technological collection technique. The Center for Biologics Evaluation and Research (CBER) currently has a program that offers electronic registration. CBER is minimizing the burden on the blood industry by sending out blood establishment registration forms asking for the information required by the regulations. All of the required information is pre-printed on the form so that the annual registrants need only record changes that have occurred.

4. Duplication of Similar Information

FDA is the only agency that requests this information. There is no similar kind of information available from any other source.

5. Small Businesses

FDA believes that the regulations should apply equally to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Training, and Manufacturers Assistance provides guidance to small businesses concerning regulatory requirements.

6. Less Frequent Collection

If collection of this data were less frequent, FDA would not benefit from research data regarding human blood and blood products. It is very important for FDA to know about the existence of all current blood establishments in order to transmit health related information to all these blood establishments. Less frequent collection would increase the likelihood that the information possessed by FDA would be incorrect or obsolete, and hinder the conduct of regulatory actions.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances

There are no special circumstances for this collection of information.

8. *Federal Register* Notice/ Outside Consultation

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment (70 FR 49655; August 24, 2005) (Tab D) was published in the ***Federal Register***. No comments were received from the public.

9. Payment/Gift to Respondent

FDA has not provided and has no intention to provide any payments or gifts to respondents.

10. Confidentiality

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and the agency's published regulations of "Public Information" under 21 CFR Part 20 which prohibit FDA from releasing to the public the names of patients, individual reporters, health care practitioners, hospitals, and any geographical identifiers. Such information is deleted from any information released by FDA under FOIA and FDA regulations.

11. Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Burden Estimate (Total Hours and Wages)

The estimated annual burden for this information collection is 1,533 hours.

Estimated Annual Reporting Burden						
21 CFR Section	**Form FDA 2830**	**No. of Respondents**	**Annual Frequency per Response**	**Total Annual Responses**	**Hours per Response**	**Total Hours**
607.20(a), 607.21, 607.22, 607.25, 607.40	Initial Registration	100	1	100	1	100
607.21, 607.22, 607.25, 607.26, 607.31, 607.40	Re-Registration	2,775	1	2,775	0.5	1,388
607,21, 607.25, 607.30, 607.31, 607.40	Product Listing Update	180	1	180	0.25	45
Total						1,533

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from the Center for Biologics Evaluation and Research's database, and FDA's experience with the blood establishment registration and product listing requirements.

The time needed for industry to complete the Form FDA 2830 is estimated to be 1 hour for new firms. The blood establishments for the most part are familiar with the regulations and registration requirements to fill out this form for the first time. Approximately 100 new Form FDA 2830's are received annually. With annual re-registration of blood establishments, the time needed for industry to complete the Form FDA 2830 is estimated to be ½ hour. The blood establishments need only to refer to their files or written instructions for a small portion of the information required. Approximately 2,775 Form FDA 2830's are received annually for re-registration. Approximately 180 Form FDA 2830's are received annually for the product listing update with an estimated average of 15 minutes to complete the form.

Cost to Respondents

The estimated annualized cost to the respondents is $72,051. This cost is based on a pay rate of $31/hour for a medical technologist, $42/hour for a supervisor, and $69/hour for a Medical Director, who may be responsible for registering an establishment, recording and listing blood products, and have the training and skills to handle various reporting requirements. The average salary of the three is $47. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	100	$47	$4,700
Re-Registration	1,388	$47	$65,236
Product Listing Update	45	$47	$2,115
Total			$72,051

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to Federal Government

The estimated annualized cost to the Federal Government is $86,764. This cost is based on 1½ Technical Information Specialists (GS-8/5) that review and process the registration forms, input the data, and maintain the database. These salary estimates include benefits but no overhead costs.

Activity	Number of FTEs	Average Annual Salary	Total Cost
Registration Form Review/Process	1.5	$57,843	$86,764
Total			$86,764

15. Program or Burden Changes

The estimated total annual burden for this information collection requirement was 1,753 hours in 2002. The current decrease to 1,533 hours (-220 hours) is attributed to a decrease in the number of blood product establishments (foreign and domestic) under initial registration and re-registration.

16. Publication and Tabulation Dates

There are no results to publish for this information collection.

17. Display of OMB Approval Date

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Explanations to "Certification for Paperwork Reduction Act Submissions"

There are no exceptions to Item 19 of OMB Form 83-I.